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| APPLICATION NO.            | FILING DATE                         | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------------------------------|----------------------|---------------------|------------------|
| 10/508,739                 | 12/30/2004                          | Antoine LaFont       | 29644/04002         | 7985             |
|                            | 7590 07/15/200<br>ΓER & GRISWOLD, Ι | EXAMINER             |                     |                  |
| 800 SUPERIOR<br>SUITE 1400 |                                     | ANDERSON, GREGORY A  |                     |                  |
| CLEVELAND, OH 44114        |                                     |                      | ART UNIT            | PAPER NUMBER     |
|                            |                                     |                      | 3773                |                  |
|                            |                                     |                      |                     |                  |
|                            |                                     | MAIL DATE            | DELIVERY MODE       |                  |
|                            |                                     |                      | 07/15/2008          | PAPER            |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  |   | Application No.                    | Applicant(s)          |  |  |  |  |
|--|---|------------------------------------|-----------------------|--|--|--|--|
| Office Action Summary  |   | 10/508,739                         | LAFONT ET AL.         |  |  |  |  |
|  |   | Examiner                           | Art Unit              |  |  |  |  |
|  |   | GREGORY A. ANDERSON                | 3773                  |  |  |  |  |
| Period fo  | The MAILING DATE of this communication app<br>or Reply  | ears on the cover sheet with the c | orrespondence address |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                    |                       |  |  |  |  |
| Status   |   |                                    |                       |  |  |  |  |
| 1) 又   | Responsive to communication(s) filed on <u>09 A</u>   | pril 2008                          |                       |  |  |  |  |
| , —  | This action is <b>FINAL</b> . 2b) This action is non-final.   |                                    |                       |  |  |  |  |
|  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                                    |                       |  |  |  |  |
| ٥/١  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.               |                                    |                       |  |  |  |  |
|  | ·   | parte Quayre, 1000 0.2. 11, 10     |                       |  |  |  |  |
| Disposit   | ion of Claims   |                                    |                       |  |  |  |  |
| 4)🛛  | )⊠ Claim(s) <u>1,3-10,19-23 and 27-36</u> is/are pending in the application.                                    |                                    |                       |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                                    |                       |  |  |  |  |
| 5)   | Claim(s) is/are allowed.  |                                    |                       |  |  |  |  |
| 6)🖂  | 6)⊠ Claim(s) <u>1,3-10,19-23 and 27-36</u> is/are rejected.   |                                    |                       |  |  |  |  |
| 7)   | Claim(s) is/are objected to.  |                                    |                       |  |  |  |  |
| 8)□  | Claim(s) are subject to restriction and/o   | r election requirement.            |                       |  |  |  |  |
| Applicat   | ion Papers  |                                    |                       |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |                                    |                       |  |  |  |  |
| •  | 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.                        |                                    |                       |  |  |  |  |
| , <u> </u>   | Applicant may not request that any objection to the   |                                    |                       |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                                    |                       |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                                    |                       |  |  |  |  |
|  |   |                                    |                       |  |  |  |  |
|  | ınder 35 U.S.C. § 119   |                                    |                       |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  |   |                                    |                       |  |  |  |  |
|  | 1. Certified copies of the priority documents have been received.   |                                    |                       |  |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No                              |                                    |                       |  |  |  |  |
|  | 3. Copies of the certified copies of the priority documents have been received in this National Stage           |                                    |                       |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                                    |                       |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                                    |                       |  |  |  |  |
|  |   |                                    |                       |  |  |  |  |
| Attachmen  | t(s)  |                                    |                       |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |                                    |                       |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date  |   |                                    |                       |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  6) Other:   |   |                                    |                       |  |  |  |  |
| Paper No(s)/Mail Date 6) LJ Other:   |   |                                    |                       |  |  |  |  |

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#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 103

**1.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1, 3-10, 19-23, and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killion 6,022,371 in view of Lafont et al 5,957,975.

Killion discloses a method for preparing an assembly for delivering a stent that is substantially resistant to negative recoil when expanded mechanically to a final predetermined diameter in a lumen of a tube, duct, or vessel of a mammalian subject, the method comprising: heating a polymeric cylindrical device which is at a final predetermined diameter and wall thickness to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the device, wherein the final predetermined diameter and wall thickness are substantially the same as the diameter and wall thickness of a stent that has been expanded to a final desired diameter at a target site in a tube, duct, or vessel of the mammalian subject, wherein the device if mounted on a solid support for maintaining the cylindrical device at the final predetermined diameter (Col. 3 II. 39-45), and wherein the polymeric device has a wall defining a first open end, a second open end, and a channel connecting the first and second open ends (Figs. 3a-3d), rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer to

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quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter (Col. 3 II. 45-49); forming slits, voids, or open spaces in the wall of the polymeric cylindrical device (Col. 3 II. 37-39); and mounting the device on an inflatable balloon catheter (Col. 3 II. 61-63). The stent will inherently exhibit positive recoil when not fully expanded.

However, Killion does not disclose reducing the diameter of the cylindrical device by heating the device to a temp at or above the Tg of the polymer while evenly applying pressure to the exterior surface of the wall of the device; and rapidly cooling the device below the Tg to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically to the final predetermined diameter by inflation of the balloon. Killion further does not disclose the stent being made from PLA.

Lafont et al. discloses reducing the diameter of the cylindrical device by heating the device to a temp at or above the Tg of the polymer while evenly applying pressure to the exterior surface of the wall of the device; and rapidly cooling the device below the Tg to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically to the final predetermined diameter by inflation of the balloon (Col. 8 II. 20-35). Lafont et al. further discloses the stent being made from PLA which has a Tg of about 60 degrees C.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the methods of Killion with the methods of Lafont et al. in order to aide in keeping the stent in place on the balloon as taught by Lafont et al. (Col. 8 II. 32-35).

## Response to Arguments

**3.** Applicant's arguments with respect to claims 1, 3-10, 19-23, and 27-36 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY A. ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

/(Jackie) Tan-Uyen T. Ho/ Supervisory Patent Examiner, Art Unit 3773